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STATE OF DELAWARE **DEPARTMENT OF STATE**

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DIVISION OF PROFESSIONAL REGULATION

PUBLIC MEETING NOTICE: BOARD OF PHARMACY

DATE AND TIME: Wednesday, June 19, 2013

PLACE: Conference Room A, Cannon Building

861 Silver Lake Blvd., Dover, DE 19904

APPROVED:

MEMBERS PRESENT

Howard Simon, R.Ph, Professional Member, President Sandra Robinson, R.Ph, Professional Member Joli Martini, R.Ph., PharmD, Professional Member Kimberly Robbins, R.Ph, Professional Member Jay Galloway, Public Member David W. Dryden, R.Ph., J.D., Executive Secretary

MEMBERS ABSENT

Matthew Maher, Public Member, Vice President Sandra Zaragoza, R.Ph, Professional Member

DIVISION STAFF/DEPUTY ATTORNEY GENERAL PRESENT

Eileen Kelly, Deputy Attorney General Theresa Newman, Administrative Specialist III Alicia Kluger, Pharmacist Compliance Officer

ALSO PRESENT

Don Holst Lisa Skedzielewski Suzanne Raab-Long Trudy Pechin Eric Branch Bill Harbestor James Park Stephanie Russo Lucy Lee Cheryl Heik Kevin Gorsline Joshua Coffield Julie Wenger Tiffany Sorey Vineykumor Prajapati Vikas Verma

CALL TO ORDER

Mr. Simon called the meeting to order at 9:30a.m.

REVIEW OF MINUTES

A motion was made by Ms. Martini, seconded by Ms. Robbins, to approve the meeting minutes for May 15, 2013 as presented, with the amendments stated by Ms. Robinson. The motion unanimously carried.

PRESIDENT'S REPORT

Mr. Simon reported that he and Mr. Dryden attended the NABP meeting in St. Louis. Bio-Similar medications, practitioners dispensing and the pseudoephedrine/ methamphetamine epidemic were among the discussion points.

Mr. Simon gave kudos to the amount of changes the board has achieved in the last year with the passing of laws as well as Rules and Regulations.

UNFINISHED BUSINESS

Complaint Status

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13-03-11 - Assigned to Hearing Officer
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13-09-11 - Assigned to Hearing Officer

13-12-11 – Forwarded to Office of Attorney General

13-19-11 – Forwarded to Office of Attorney General

13-02-12 – Forwarded to Office of Attorney General

13-03-12 - Closed

13-04-12 - Assigned

13-05-12 - Assigned

13-07-12 - Assigned

13-09-12 – Assigned

13-01-13 – Forwarded to Office of Attorney General

13-02-13 - Assigned

13-03-13 - Assigned

13-04-13 - Assigned

13-05-13 – Assigned

13-06-13 - Assigned

13-07-13 - Assigned

13-08-13 - Assigned

13-09-13 - Assigned

13-10-13 - Assigned

Prescription Monitoring Program (PMP) Update

Ms. Nettesheim reported that the Delaware PMP has over 1700 registrants. She is currently working with the New Jersey PMP on a Memorandum of Understanding to share PMP data, which will ideally be available in December 2013.

Ms. Nettesheim also advised the board of the interconnect status, advising that they are currently working on the PMP statue change of 16 Del.C § 4798, to contain stronger language regarding to the allowance of Delaware to share information with other states.

Deliberation on Public Comments Received on Proposed Regulations

Ms. Kelly advised there were no public comment at the Rules and Regulations hearing, nor were there any written comments sent in within the 15 day written comment period after the hearing.

Ms. Robinson suggested, striking the phrase "only to patients that are self medicated".

Ms. Kelly advised the board that changes made would prevent the signing of the Rules and Regulations, and the board will need to convene for another hearing.

A motion was made by Ms. Robbins, seconded by Ms. Martini, to republish the Rules and Regulations in the Register of Regulations, with amendments as discussed. The motion unanimously carried.

Discussion of Patient Counseling Regulation and Statute Language

Ms. Kluger suggested adding the definition of Patient Counseling to the laws. After review the board requested that Ms. Kluger and Mr. Dryden to draft a definition to amend to the Rules and Regulations.

NEW BUSINESS

Pharmacist and Intern Licensure Approval Ratifications

A motion was made by Ms. Robinson, seconded by Ms. Robbins, to ratify the approval of the Pharmacist applications of Rina Kelley, Na'Teka Shelton, Chad Forinash, David Dinh, and Gary Sobocinski. The motion unanimously carried.

A motion was made by Ms. Martini, seconded by Ms. Robinson, to ratify the approval of the Intern Pharmacist applications of Viha Dave, Robert Wright, and Laura Wolfe. The motion unanimously carried.

Non-Resident Pharmacy Licensure Approval Ratifications

A motion was made by Mr. Galloway, seconded by Ms. Robbins, to ratify the approval of the non-resident pharmacy applications of Green Valley Drugs, Goot Nursing Home Pharmacy, Inc., Walgreen Co., Mead Square Pharmacy, Inc., Prescription Dynamics, Inc., Arrow Pharmacy Holdings, LLC, HomeChoice Partners, Inc., and Pharmaceutical Specialties, Inc. The motion unanimously carried.

Wholesale Distributor Licensure Approval Ratifications

A motion was made by Mr. Galloway, seconded by Ms. Robbins, to ratify the approval of the wholesale distributor applications of DPT Laboratories, Ltd., Antigen Laboratories, Watson Pharma, Inc., Grifols USA, LLC, and Matheson Tri-Gas, Inc. The motion unanimously carried.

Retail Pharmacy Licensure Approval Ratification

A motion was made by Mr. Galloway, seconded by Ms. Robbins, to ratify the approval of the retail pharmacy applications of Delaware CVS pharmacy, CVS Pharmacy #6869, and Christiana care Pharmacy – Wilmington. The motion unanimously carried.

Medical Gas Dispensers

A motion was made by Mr. Galloway, seconded by Ms. Robbins, to ratify the approval of the Medical Gas Dispenser applications of Tri County Medical Equipment & Supply and Personal Support Medical Suppliers. The motion unanimously carried.

Pharmacist-In-Charge Interviews

A motion was made by Ms. Martini, seconded by Ms. Robinson to add Lisa Skedzielewski to the agenda as 5.4.3. The motion unanimously carried.

Ms. Robbins conducted a PIC interview for Vinaykumar Prajapati. He is employed by Walmart Pharmacy #10-1741

Ms. Robbins conducted a PIC interview for Vikas Verma. He is employed by Walmart Pharmacy #10-5436.

Ms. Robbins conducted a PIC interview for Lisa Skedzielewski. She is employed by Walgreens Pharmacy #12040.

Consultant Pharmacist Interview

Ms. Robbins conducted a Consultant Pharmacist interview for Joshua Coffield. He is employed by Cardinal Health at the DE Hospital for the Chronically III in Smyrna.

Collaborative Practice Review

Julie Wenger, from the National Association Chain Drug Stores and Kevin Gorslive, from Rite Aid, discussed collaborative agreement practices. Ms. Wegner read a letter to the board stating their proposal. Ms. Kelly will review the issue to insure whether the change would need to be a statutory change or a regulation change. Mr. Dryden will also gather items that were presented previously regarding this matter.

Board Election of Officers

A motion was made by Ms. Robinson, seconded by Mr. Galloway to elect Joli Martini as the Board's President and Kimberly Robbins as the Vice President. The motion unanimously carried.

COMMITTEE REPORTS

Legislative – Sandy Robinson, Howard Simon, Jay Galloway, Kim Robbins and David Dryden:

Mr. Dryden provided an update of HB 154 (CE Diversion Bill), HB 130 (Pseudoephedrine), SB 73(Syringe), SB 59, SB 119 (hospice), SB 118 (Bio-Similar), and SB 90 (unlicensed practice).

Continuing Education – Sandy Robinson and Joli Martini:

Ms. Robinson advised that ACPE has a suffix of HO5, to qualify as a medication safety/ medication error continued education credit. The Board will review each course taken on a case by case basis to accept safety/ medication error CE, which does not have a HO5 suffix on the certificate. The CE will be monitored by the random audit conducted by the Division of Professional Regulation.

Those who attended the Attorney General Summit did not receive a number on the certificate for proof of continued education. The Board advised for those who attended, keep the record of the certificate, and if they are chosen for audit, the continued education certificate will provide substantial proof of completion.

Consumer Affairs – Matthew Maher and Jay Galloway:

No report.

Professional Liaisons – Sandy Robinson and Sandra Zaragoza:

Ms. Robinson reported she has not received any information for the program DHSP but when she receives the information she will report.

Ms. Robinson attended the DPS meeting. A board report was submitted by Ms. Robinson.

Controlled Substance Liaisons – Howard Simon, Jay Galloway and David Dryden:

Mr. Simon stated the next meeting is scheduled for August 28, 2013.

COMMITEE UPDATES REGARDING PROPOSED REGULATIONS

USP 795 & 797 Committee – Sandy Robinson, Howard Simon, Alicia Kluger, Brenda Pavlic, Sandra Zaragoza, Hooshang Shanehsaz, Calvin Freedman and David Dryden:

The Board is waiting for the FDA amendments.

Immunization/Pen Needle Committee – Howard Simon, Kim Robbins, Mark Freebery and David Dryden:

No report.

Pharmacy Technician Registration Committee – Howard Simon, Matt Maher, Sandy Robinson, Kim Robbins, Kevin Musto, Maryanne Holzapfel and David Dryden:

The next meeting will be held on August 21, 2013 at 11:00 a.m.

BOARD CORRESPONDENCE

2013 NABP Program Review and Training Session

Mr. Dryden read the correspondence from NABP, dated June 13, 2013, regarding the upcoming NABP training session. Two representatives will attend the meeting to gain additional knowledge of products and features NABP offers to enhance the internal process of applications.

Mr. Dryden advised at the NABP annual meeting, delegates from the Board of Pharmacy voted to pass resolution to 109-1-13, Pharmacy Compounding and Sterile Products, recognizing the need to protect the public's health and safety.

APN Consensus Model Bill

Mr. Dryden advised the Board that the Board of Medical Practice sent a letter to the Board of Nursing to advise they do not support the nursing endeavor.

EXECUTIVE SECRETARY AND INSPECTION REPORT - David Dryden, Samantha Nettesheim and Alicia Kluger

The following inspections and activities were completed during the last 30 days:

- 3 routine pharmacy inspections
- 2 pharmacy opening inspection
- 1 pharmacy remodel
- Inspected random inspection of Treatment Centers

During the last 30 days there were no theft/loss or robberies reported.

Ms. Kluger reported we have received a 38% response to the Delaware survey which was to be completed by all resident and non-resident pharmacies. Out of the response that was received 9 out of 13 licensed hospitals, compound sterile products; out of 207 active licensed retail stores, 8

Board of Pharmacy Minutes – June 19, 2013 Page 6

have reported they also compound sterile products; and out of 540 active Non-Resident Pharmacies, 56 responded thus far to compounding sterile products.

NEWSLETTER UPDATES

No report.

OTHER BUSINESS BEFORE THE BOARD

Ms. Robinson advised the Board that the Deputy Attorney General's office may be considering a request to have deliberations in private. The concern is whether or not there is a violation of HIPPA laws regarding the Board discussing matters within the meetings. Ms. Kelly will look further into the matter.

PUBLIC COMMENTS

None.

NEXT SCHEDULED MEETING

The next meeting is scheduled for August 21, 2013.

ADJOURNMENT

There being no other business before the Board, a motion was made by Ms. Martini, seconded by Ms. Robinson, to adjourn the meeting. The meeting was adjourned at 10:55am.

Respectfully submitted,

Theresa Newman

Administrative Specialist II

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